

Rebekah Conroy  
**STONE CONROY LLC**  
25A Hanover Road  
Suite 301  
Florham Park, NJ 07932  
(973) 400-4181

OF COUNSEL:

Jay Lefkowitz, P.C.  
Jeanna M. Wacker, P.C.  
Mira A. Mulvaney  
**KIRKLAND & ELLIS LLP**  
601 Lexington Avenue  
New York, NY 10022  
(212) 446-4800  
*Attorneys for Plaintiffs*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ACROTECH BIOPHARMA LLC. and  
CYDEX PHARMACEUTICALS, INC.,

Plaintiffs,

v.

ALEMBIC GLOBAL HOLDING SA,  
ALEMBIC PHARMACEUTICALS, LTD.  
and ALEMBIC PHARMACEUTICALS,  
INC.,

Defendants.

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Civil Action No. 20-CV-19295

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**CONSENT JUDGMENT**

WHEREAS Plaintiffs Acrotech Biopharma LLC and Cydex Pharmaceuticals, Inc. (collectively, “Acrotech”) and Defendants Alembic Global Holding SA, Alembic Pharmaceuticals Ltd. and Alembic Pharmaceuticals Inc. (collectively, “Alembic”) have agreed to terms and conditions representing a negotiated resolution of Civil Action Nos. 20-CV-19295 (D. N.J.); and

WHEREAS the following definitions shall apply to this Consent Judgment:

- a. “the ‘183 Patent” means U.S. Patent No. 10,864,183;
- b. “Alembic ANDA Product” means the product described in Abbreviated New Drug Application No. 212810, including 50 mg/vial generic versions of EVOMELA® (Captisol®-enabled Melphalan HCl), existing on the Effective Date, and as amended or supplemented from time to time in the ordinary course of business; and
- c. “Affiliate” means any entity controlling, controlled by, or under common control with a Party, but only as long as such control continues, where “control” means: (a) the ownership of more than fifty percent (50%) of the equity or beneficial interest of such entity, or the right to vote for or appoint a majority of the board of directors or other governing body of such entity; or (b) the power to directly or indirectly direct or cause the direction of the management and policies of such entity by any means whatsoever;

The parties, by their respective undersigned attorneys, hereby stipulate and consent to entry of judgment in this action as follows:

IT IS HEREBY ORDERED, ADJUDGED AND DECREED that:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over the parties.
2. The ‘183 patent is valid, enforceable, and infringed by the Alembic ANDA Product.

3. Unless specifically authorized or otherwise modified between the parties, Alembic, including any of its successors and assigns, is enjoined from making, having made, using, selling, offering to sell, importing or distributing the Alembic ANDA Product in the United States, on its own or through any Affiliate, officer, agent, servant, employee or attorney, or through any person in concert or coordination with Alembic or its Affiliates, until such date permitted by the Settlement Agreement that the Parties have entered into.

4. Nothing herein prohibits Alembic or its Affiliates from maintaining a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. §314.94(a)(12) with respect to the '183 Patent.

5. Nothing herein restricts or is intended to restrict the U.S. Food and Drug Administration from approving ANDA No. 212810.

6. This Court retains jurisdiction to enforce performance under this Consent Judgment and any related agreement(s). The Parties agree that, in the event of violation of the terms of this Consent Judgment or any related agreement(s), this Court has personal jurisdiction over the parties and venue for an action to enforce performance under this Consent Judgment, including for a preliminary injunction against the breaching conduct and the Parties hereby waive any and all defenses based on lack of personal jurisdiction or venue.

7. The Complaint in Civil Action No. 20-CV-19295 (D.N.J.) and all remaining claims, counterclaims, or affirmative defenses in these actions, are dismissed without prejudice and without costs, disbursements, or attorneys' fees to any party.

Dated: June \_\_, 2021

Respectfully submitted

/s/Rebekah Conroy

Rebekah Conroy  
STONE CONROY LLC  
25A Hanover Road

/s/Douglas R. Weider

Douglas R. Weider  
GREENBERG TRAURIG, LLP  
500 Campus Drive, Suite 500

Suite 301  
Florham Park, NJ 07932  
(973) 400-4181

*Attorney for Plaintiffs*

Florham Park, NJ 07932  
(973) 360-7900

*Attorney for Defendants*

OF COUNSEL:

Jay Lefkowitz, P.C.  
Jeanna M. Wacker, P.C.  
Mira A. Mulvaney  
**KIRKLAND & ELLIS LLP**  
601 Lexington Avenue  
New York, NY 10022  
(212) 446-4800

OF COUNSEL:

Richard C. Pettus  
**GREENBERG TRAURIG, LLP**  
200 Park Avenue  
New York, NY 10166  
(212) 801-9200

**SO ORDERED** this 3<sup>rd</sup> day of June, 2021.

/s/ FRED A. L. WOLFSON

**UNITED STATES DISTRICT COURT  
JUDGE**